

Clearance of Clopidogril

*406. SHRI MUNAVVAR HASAN:

SHRI VIJAY SINGH YADAV:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) what is the time taken for granting approval for new drugs;
- (b) whether it is a fact that Clopidogril, a new drug, was approved by DCGI within three days of submission of clinical trials;
- (c) if so, whether the DCGI office approves all new drugs in such a short-time; and
- (d) the names of new drugs cleared during 2000 and the time taken to grant first approval, after submission of clinical trial reports for each drug?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR): (a) to (d) The time taken for evaluation of new drug applications varies according to the nature of the molecule/ drug. Evaluation of a new drug application is a complex process and the details are spelt out in Scheduled Y of the Drug and Cosmetic Rules, 1945. The modalities involved would *inter-alia* include initial evaluation by experts of chemical and physical characteristics, animal toxicity, pharmacokinetics and pharmacodynamics of the drug, approval of protocols for clinical trials as well as data generated by the various clinical trials, results of testing of the new drug by the Central Government Drug lab, etc.

Therefore, depending upon the nature of the application, it may normally take more than 5 years for approval of investigational new drug (A drug molecule not tested on human beings anywhere in the world), about 1—3 years for the first time approval of the drug already approved elsewhere and about 2-3 months for subsequent applications for already approved drugs. This is, however, subject to submission of all required data as per provisions of Schedule Y of Drug and Cosmetic Rules. In the case of certain critical drugs, which have been already approved elsewhere in developed countries, and

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which are of importance from the point of view of Public Health, clearance is also given on a fast track basis without doing local clinical trials.

The application from M/s Torrent Pharmaceuticals Ltd. for approval of Clopidogril was received on 5.7.2000. This was a drug already approved abroad. Permission to undertake phase-Ill clinical trials and tab testing for quality from the Central Government laboratory, Kolkota, was given on 3.10.2000. The report from Central Drug Laboratory declaring the drug as of standard quality was received on 4.12.2000. The data from the clinical trials was received on 5.1.2001. After evaluating the data, the drug was approved on 1.2.2001. Hence the concern that approval for Clopidogril was given within three days of submission of clinical trials is not factually correct.

Details of New Drugs cleared during the year 2000, alongwith date of first approval granted and date of submission of report on clinical trials, is given in the Statement. (*See below*) The time taken between date of approval and receipt of the report on clinical trials varies since data relating to quality is also subject to receipt of data regarding Quality Control from the Central Drug labs.

Statement*New Drugs approved by Drug Controller General (India) during the period /artuary-2000 to December-2000*

S. No.	Name of the Drug	Category	OT Reports Reed, on	Date of Approval	Comment CDL Report Reed, on
1.	Oxiconazole	Anti-fungal	03/05/1999	17/01/7000	07/12/1999
2.*	Temozolamide	Anti-cancer	—	17/01/7000	—
3.	Olanzapine	Anti-Psychotic	04/11/1999	27/01/2000	—
4.	Fluvoxamine Maleate	Anti-Depressant	07/01/2000	21/02/2000	—
5.	Celecoxib	Nsaid	18/01/2000	22/02/2000	—
6.*	Nevi-Rapine	Anti-HIV	—	06/03/2000	—
7.	Repaglinide	Anti-Diabetic	09/10/1999	23/03/2000	09/03/2000
12	8.* Ganciclovir	Anti-Viral	—	04/04/2000	—
	9.* Trapidil	Adjunct in Angioplasty	—	11/05/2000	—
	10. Rofecoxib	Nsaid	14/06/2000	26/06/2000	—
	11. Rosiglitazone Maleate	Anti-Diabetic	13/06/2000	28/06/2000	—
	12. Irbesartan	Anti-Hypertensive	17/05/2000	26/06/2000	—
	13. Granisetron	Anti-Emetic	02/05/2000	05/07/2000	—
	14.* Rituximab	Anti-Cancer	—	10/07/2000	—
	15.* Trastuzumab	Anti-Cancer	—	10/07/2000	—
	16. Moclobemide	Anti-Depressant	26/D6/2000	2a/07/2000	—

17.	Candesartan	Anti-Hypertensive	28/07/2000	31/08/2000	—
18.	Venlafaxine HCL	Anti-Depressant	24/08/2000	18/09/2000	—
19.	Paroxetine HCL	Anti-Depressant	25/08/2000	04/10/2000	—
20.*	Iomeprol	Contrast Medium		05/10/2000	—
21.*	Capecitabine	Anti-Cancer		12/10/2000	—
22.*	Dacilizumab	Immuno Supressive Agent		12/10/2000	—
23.*	Didanosine	Anti-HIV		15/10/2000	—
24.	Pioglitzone HCL	Anti Diabetic	29/08/2000	17/10/2000	—
25.	OCTY. Lonium Bromide FORI. B.S. (Irritable Bowel Syndrome)		11/09/2000	15/12/2000	—
13	Parvastatin	Lipidlowering Agent	19/09/2000	21/12/2000	04/12/2000

*Marked drugs mentioned above are either anti-cancer/anti-Aids or immunosuppressive agent which are life saving drugs and it is also difficult to conduct clinical trials with such drugs because of ethical reasons. Therefore these drugs are approved on the basis of recommendations of experts.